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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,658	11/29/2001	James M. Coull	BP0002-US	5256

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,658	COULL ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *51-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 51-59 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 March 2004.

Specification

2. The specification is again objected to as documents have been improperly incorporated by reference. In particular, the specification states at pages 8, 11, 13, 14, and 17 that numerous US Patents, various foreign patent publications, and some non-patent literature have all been incorporated by reference, however, the specification fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun*

> *Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of

ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

5. For convenience, claims 1, 18, and 235, the only independent claims under consideration, are reproduced below.

1. A method for determining an organism of interest in a sample from another organism or organisms to be distinguished; said method comprising:

treating the sample, or a portion thereof, with at least one detectable molecular probe wherein the molecular probe or probes are selected such that either:

(i) both the organism of interest and the other organism or organisms react with the molecular probe in a way that produces detectable organisms of interest and a detectable other organism or organisms to be distinguished; or

(ii) only the organism of interest reacts with the molecular probe in a way that produces only detectable organisms of interest; and

contacting the sample, or a portion thereof, with a solid carrier to which has been immobilized a binding partner such that if (i) applies then the binding partner is chosen to be reactive only with the detectable organism of interest but not reactive with the detectable other organism or organisms to be distinguished; but if (ii) applies then the binding partner is chosen to be generally reactive with the detectable organism of interest but also may be reactive with the other organism or organisms to be distinguished; and

determining the presence, absence, position or number of detectable organisms immobilized to the solid carrier and correlating the result with the presence, absence, or number of the organisms of interest in the sample, or portion thereof.

18. A method for sorting and determining an organism or organisms of interest in a sample or samples; said method comprising:

treating the sample or samples, or a portion thereof, with one or more detectable or independently detectable molecular probes wherein the one or more molecular probes are selected such that either:

(i) the detectable probe or probes react with the different organisms to be determined in a way that produces different detectable organisms that possess the same stain; or

(ii) the independently detectable probes react with the different organisms to be determined in a way that produces different independently detectable organisms that possess an independently detectable stain; and

contacting the sample or samples, or a portion thereof, with one or more different types of coded beaded supports, wherein each different type of coded beaded support can be independently determined in a suitable particle sorter and wherein to the coded beaded supports have been immobilized one or more binding partners chosen to select a particular organism or organisms such that the detectable or independently detectable organisms become selectively bound to the coded beaded supports as a result of the occurrence of specific binding partner interactions;

sorting the different types of coded beaded supports in a suitable particle sorter; and

determining the presence, absence, or number of detectable organisms, or each of the independently detectable organisms, immobilized to each different type of coded beaded support and either: (iii) correlating the result with the particular binding partner immobilized to each particle type to thereby determine the presence, absence or number of each of the different organisms of interest in the sample, or portion thereof; or (iv) correlating the result with the code for a sample source from which the sample, or portion thereof, was derived to thereby determine the presence, absence or number of each of the different organisms of interest in each different sample, or portion thereof.

35. A method for sorting and determining different organisms of interest in a sample; said method comprising:

treating the sample, or a portion thereof, with one or more detectable or independently detectable molecular probes wherein the one or more molecular probes are selected such that either:

(i) the detectable probe or probes react with the different organisms to be determined in a way that produces different detectable organisms that possess the same stain; or

(ii) the independently detectable probes react with the different organisms to be determined in a way that produces different independently detectable organisms that possess an independently detectable stain; and

contacting the sample, or a portion thereof, with a solid carrier array to which binding partners have been immobilized at unique identifiable locations such that the detectable or independently detectable organisms are selectively bound to the locations on the array as a result of the occurrence of specific binding partner interactions; and

determining the presence, absence or number of the detectable or independently detectable organisms immobilized at the many different locations of the array and correlating the result with the particular binding partner immobilized to each location on the array to thereby determine the presence, absence or number of the different organisms of interest in the sample.

6. For purposes of examination, said claims 1-50 have been interpreted as allowing for determining the "presence, absence, position or number of detectable organisms...wherein the molecular probe stains all organisms of a domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype or strain without regard to whether or not this represents the organism of interest and wherein the binding partner is specific for the domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype or strain that is the organism of interest" (claim 12). As seen in claim 6, the binding partner can be an antibody; and in claim 28,

the "binding partner" can be "a carbohydrate, a lectin, a peptide, a receptor, a charged polymer and a protein.

7. A review of the specification fails to find an adequate written description of any molecular probe and binding partner that are to be used in the claimed invention. At best, the specification provides motivation for others to develop such molecular probes and binding partners that could be used in the claimed method, however, providing motivation for others to develop such essential starting materials does not reasonably suggest that applicant, at the time of filing, was in possession of the invention as claimed nor satisfy the written description requirement of 35 UWSC 112, first paragraph.

8. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

9. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

10. Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

11. It is well settled that one cannot enable that which they do not yet possess. As presented above, the specification does not provide an adequate written description of the claimed invention so as to reasonably suggest that applicant was in possession of the invention at the time of filing. Further, the specification does not provide the essential starting materials or reaction

conditions that must be employed when practicing the claimed invention. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

12. As set forth at page 2 of the disclosure, the area of art to which the invention belongs is recognized as being wrought with "difficulties associated with specificity, sensitivity, and/or

reliability" of nucleic acid probe-based assays (specification at page 2, lines 23-24). As seen in claims 1, 2, 4, 5, 7-19, 21, 22, 24-36, 38, 39, and 41-50 fairly encompass the use of these very nucleic acid probes. While claims 3, 6, 20, 23, 37, and 40 recite the use of a peptide nucleic acid, the claim does not require that the conditions of its use be such that non-target nucleic acids form a complex with said probes, and in so doing result in the generation of useless results. Even if the claims were to be limited to the use of PNA probes, the specification does not teach which probes are to be used, much less which probes are to be used in combination with various molecular probes so that every "species, taxon, subclass, subspecies, serotype or strain" of the organisms of interest can be identified.

13. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

At pages 3-9 of the response to the Office action mailed 27 July 2004 applicant's representative offers opinion as to what is well known in the art, to what degree a skilled artisan would interpret the description provided, as well as opinion statements as to what is within the level of skill of the ordinary artisan. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of

attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

14. For the above reasons, and in the absence of convincing evidence to the contrary, the rejections are maintained.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
18 April 2005